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News We're Watching: DMCA Judicial Review Upheld; Abbott's Rio CGM Available OTC; J&J's Velys Wins FDA UKA Expansion

by Marion Webb

This week, AdvaMed and MITA win appeal to prevent repair companies from hacking medical devices, the FDA cleared Abbott's Libre Rio CGM for OTC sales, J&J MedTech wins expanded clearance for Velys knee medical robot, the FDA updates its AI program, Canary Speech secures $13m in series A funding and Xeltis won FDA approval for an IDE submission to begin enrolling patients for a pivotal study for aXess.

Win For MITA And AdvaMed In DMCA Lawsuit

AdvaMed and the Medical Imaging & Technology Association won an appeal from the Washington DC Court of Appeals about a case concerning repair companies from hacking medical devices.

The case lies in the Digital Millennium Copyright Act (DMCA), the Administrative Procedure Act (APA) and the Library of Congress.

The 7 June appeals decision affirms the ability of federal courts to review federal rules. AdvaMed and MITA originally filed a lawsuit against the Library of Congress after the Librarian used a DMCA provision that allowed access to software of medical devices. AdvaMed and MITA argued that this was a violation of the APA.

The case "raises the question of whether copyright rules promulgated under the Digital Millennium Copyright Act ("DMCA") are reviewable under the Administrative Procedure Act," the *DC Circuit Court opinion* explains.

In March 2023, the DC District Court ruled against AdvaMed, saying that the APA doesn't authorize lawsuits of Congress, which extends to the Librarian of Congress.

AdvaMed and MITA appealed, saying that the Library of Congress was an agency subject to APA, an opinion that was upheld by the DC Circuit Court.

Chistopher White, AdvaMed chief policy officer said in a *release*: “The ruling ensures that regulatory actions affecting our industry are subject to judicial review, thereby protecting the innovation and safety standards.”

J&J MedTech Wins Expanded Clearance For Velys Robot

The US Food and Drug Administration has granted an expanded 510(k) indication for *Johnson & Johnson (Pty) Ltd* MedTech's robotic-assisted solution Velys in unicompartmental knee arthroplasty (UKA), or partial knee replacement.

This builds on Velys robotic-assisted solution used in total knee replacement, which has been cleared in 20 markets and is used in over 55,000 procedures.

The UKA application is indicated for both medial and lateral procedures to better enable surgeons to guide precise implant placement without a CT scan. Velys, according to J&J MedTech, equips surgeons with the information they need to help preserve the soft tissue envelope, predict joint stability, and work toward returning knee function.

FDA Updates Its Artificial Intelligence Program

The FDA has added *six new web pages* to the Office of Science and Engineering Laboratories (OSEL) regulatory science research activities related to the agency’s artificial intelligence and machine learning initiatives.

The agency’s Artificial Intelligence Program, which is part of the Center for Devices and Radiological Health (CDRH), conducts regulatory science research to ensure patient access to safe and effective AI/ML medical devices. The agency’s AI program is one of 20 research programs in the device center’s OSEL.

The FDA says AI technologies are transforming health care by producing diagnostic, therapeutic, and prognostic medical recommendations and decisions informed by the vast amount of data generated during the delivery of health care.

One of the major goals of the AI program, the agency says, is to fill “major regulatory science gaps” by developing robust AI test methods and evaluation methodologies for assessing AI performance both in premarket and real-world settings to reasonably ensure the safety and effectiveness of novel AI algorithms.

Canary Speech Secures $13M In Series A funding

Canary Speech, an AI-powered voice biomarker health tech company, announced on 12 June it secured $13m in a series A funding round led by Cortes Capital, LLC (Love’s Private Equity) with participation from Sorenson Communications, LLC, SMK and Hackensack Meridian Health.

The company said it aims to “expand the team to support the accelerating growth driven by

advancements in artificial intelligence and the health care industry's demand for more advanced tools."

Canary's voice biomarker technology has a wide range of applications within health care. It is developing algorithmic models for detecting behavioral health, progressive neurological and cognitive diseases based on a 40-second recording of speech. (Also see "*Canary Speech's Voice AI Can Help Detect Alzheimer's With 40-Second Conversation*" - Medtech Insight, 23 Feb, 2024.)

Abbott's Libre Rio Lands OTC Clearance

The US FDA has cleared *Abbott*'s Libre Rio blood glucose monitor for over-the-counter sale. This is Abbott's second OTC blood glucose device to get a regulatory thumbs-up in recent succession, following the clearance of the Lingo blood glucose monitor earlier this month. (Also see "*Abbott's Lingo Becomes Second FDA-Cleared OTC Blood Glucose Monitor*" - Medtech Insight, 4 Jun, 2024.)

While Lingo is being marketed as a tool for any adult who wants to track their blood glucose levels for wellness purposes, Libre Rio is intended for use by adults with Type 2 diabetes who do not use insulin and typically manage their diabetes through lifestyle modifications. The company believes that the new regulatory status may make it easier for people with diabetes to try CGM technology.

Both products are based on technology from Abbott's FreeStyle Libre continuous glucose monitor, which were previously available only with a prescription in the US. However, Abbott says Libre units are already sold over the counter in more than 50 countries and are used by about 6 million people worldwide.

The new products should expand the appeal of the CGM technology, Abbott said in a statement.

"There is no one-size-fits all approach for glucose monitoring, which is why we've designed different products for different people – all based on the same world-leading biowearable technology," said Lisa Earnhardt, executive vice president and group president of Abbott's medical devices business. "People living with diabetes need certain features like tracking medications or sharing data with a health care provider. People without diabetes need different features to manage their metabolic health, including personalized coaching to promote actionable lifestyle changes."

FDA Approval Pivotal Study For 'Restorative' Hemodialysis Vascular Access Implant

Xeltis AG, which develops transformative implants that enable the natural creation of living and long-lasting vessels, announced on 13 June it received approval from FDA for an Investigational Device Exemption (IDE) submission to begin enrolling patients into a pivotal study for aXess.

aXess is a "restorative" implantable blood vessel for hemodialysis vascular access. The aXess implant is made from synthetic supramolecular polymers, designed to be absorbed by the body and gradually replaced by patients' living tissue, creating permanent blood vessels.

Annually, three million individuals are diagnosed with end-stage renal disease and require hemodialysis, which involves an external blood filter connected to the blood circulation through a vascular access in the patient's arm or neck, Eliane Schutte, CEO of Xeltis, told Medtech Insight.

Three common vascular access types are created through surgery: artery vein (AV) fistula; artery vein (AV) graft; and central venous catheter.

"A safer and more durable option is needed to reduce the burden and risks associated with hemodialysis," said Schutte. The current options carry the risk of infections and blood clots. In the case of arteriovenous fistula, it often fails to mature, she continued.

"We have already shown outstanding 12-month data from our first-in-human study in Europe and are looking forward to starting this pivotal trial in the US," said Schutte.

In the US trial, the company aims to replicate the clinical outcomes observed in its European trial.

The first in-human trial in Europe ran for one year and involved 20 patients. The data revealed a secondary patency rate of 100% (meaning the implant achieved adequate blood flow), no infections related to cannulation were recorded and fewer interventions were needed compared to the standard of care.

"The primary objective of the US trial is to assess the 12-month secondary patency rates. We seek to show an improved safety profile concerning infection rates compared to existing performance goals and enhanced health economics over the standard of care," said Schutte.

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